K083152

Plastmed
A MEDICAL DEVICE COMPANY

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Tefen Industrial Park
24959, Israel
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FEB - 2 2009

510(K) SUMMARY

510(k) Number K_____

Applicant's Name: Plastmed Ltd.
Tefen Industrial Park
P.O.B 26, ISRAEL
Tel: (972)4-987-3737
Fax: (972)4-987-3001

Contact Person: Elissa Burg
Tefen Industrial Park
P.O.B 26, ISRAEL , 24959
Tel (972)4-987-3737; Fax (972)4-987-3001
qa@plastmed.com

Trade Name: *EQUASHIELD*™ system

Common name: Closed drug transfer system

Classification:
Name: Intravascular administration set
Product Code: LHI
Regulation No: 880.5440
Class: II
Classification Panel: General hospital

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

1. PhaSeal closed system for the preparation and administration of parenteral drugs; Carmel Pharma AB K972527
2. TEVADAPTOR; Migada Plant K051669
3. Texium™ Syringe; Cardinal Health, Aleris® Products K071108

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Device Description:

EQUASHIELD™ is a closed system for drug transfer and reconstitution. The EQUASHIELD™ system consists of an adaptor to the medication vial (Vial Adaptor), a proprietary piston syringe (Syringe Unit), an adaptor for connection to the infusion bag for injection (Spike Adaptor 1), an adaptor for connection to the infusion bag for withdrawal (Spike Adaptor W) and an adaptor to the Luer Lock (Luer Lock Adaptor).

The EQUASHIELD™ system is a closed system – it prohibits the escape of hazardous drugs and vapors to the surrounding environment, by air-tight enclosing of air and all contaminants within the system.

Indication for Use Statement:

The EQUASHIELD™ Drug Reconstitution and Transfer System is a contained system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs, for intravenous infusion or injection

Performance Validation:

Performance Testing – bench tests

A series of bench tests were performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

Performance Testing – Simulated clinical test

A simulated clinical test was performed in order to evaluate the Plastmed EQUASHIELD™ System and to ensure it performs its intended use as a closed drug transfer system. The simulated test has

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demonstrated that the EQUASHIELD™ system performs its intended use.

Tests conclusion:

Both bench tests and simulated clinical test have shown that the device performs its intended use.

Materials:

Materials of the *EQUASHIELD*™ device are biocompatible in accordance with ISO 10993-1.

Substantial Equivalence:

We have demonstrated that the *EQUASHIELD* ™ meets its labeled performance claims, and that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

Ms. Elissa Burg
Quality Assurance and Regulatory Assurance Manager
Plastmed Limited
Building No. 7
P.O.B 26
Tefen Industrial Park
ISRAEL 24959

Re: K083152
Trade/Device Name: EQUASHIELD™ System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: December 25, 2008
Received: December 29, 2008

Dear Ms. Burg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: EQUASHIELD ™ System

Indications for Use:

The EQUASHIELD™ Drug Reconstitution and Transfer System is a contained system to be used by pharmacists or other healthcare professionals to prepare drugs, including cytotoxic drugs, for intravenous infusion or injection.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Division of General, Restorative and Neurological Devices

510(k) Number

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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